

# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/009,583 03/19/2002 8830-10 (157952) 1753 Louise Georgina Buttle EXAMINER 23973 01/27/2005 7590 DRINKER BIDDLE & REATH YOUNG, MICAH PAUL ATTN: INTELLECTUAL PROPERTY GROUP ART UNIT PAPER NUMBER ONE LOGAN SQUARE 18TH AND CHERRY STREETS 1615 PHILADELPHIA, PA 19103-6996

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/009,583	BUTTLE, LOUISE GEORGINA
	Examiner	Art Unit
	Micah-Paul Young	1615
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on <u>18 June 2004</u> .		
	is action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
<ul> <li>4)  Claim(s) 1.3.4 and 12 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1.3.4 and 12 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>		
Application Papers		
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ol>	Paper No(s)/Mail Da  5) Notice of Informal Pa  6) Other:	te atent Application (PTO-152)

#### **DETAILED ACTION**

Acknowledgment of Papers Received: Petition entered 6/18/04, Petition Decision entered 11/18/04.

### Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 1, 3,4,and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwahashi et al (XP 000939130). The claims are drawn to a method of feeding fish cholesterol in order to improve their pigment.

The reference teaches methods for improving the pigment of fancy carp, by including cholesterol and a pigment into their feed compositions (Abstract). The carp were split into 10 separate groups with each given different amounts of various combinations of pigment and cholesterol. Group 8 was given a combination of astaxanthin and cholesterol (Table I). The researchers observed an increase in the intensity of the redness of the fancy carp after the feeding (Table 4). In Group 8 the accumulation rate of carotenoids was 1.41 % (Table 7).

What is lacking in the reference is physical form of the feed composition. This however would be obvious to a skilled artisan since most feed compositions are presented in pellet, of tablet form. Also the concentration of cholesterol is slightly higher than that of applicant.

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Though the reference does not disclose the specific concentrations of the claimed invention, applicant is reminded that it is well within the level of ordinary skill in the art to find the optimal working ranges for a composition. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various feed compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

It is the position of burden must be shifted to applicant to provide a patentable distinction and criticality to the inclusion of cholesterol into the feed composition. Referring to the specification, there appears to be no statistically significant difference between the feed compositions examiner that

With this in mind a skilled artisan would have followed the suggestions and teachings of the art. A skilled artisan would have been motivated by the teachings of Iwahashi to optimize the concentrations of pigment and cholesterol, in order to improve the flesh color of fancy carp, or any fish benefiting from increased pigmentation. These fish are more appealing to consumers, and are easier to market to consumers. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow these teachings and suggestions with an expected result of a method to improve pigmentation and feed composition to do so.

## Response to Arguments

1. Applicant's arguments filed 3/11/04 have been fully considered but they are not persuasive. Applicant argues that:

a. The cholesterol enhances the uptake of carotenoids, where the prior art does not teach this property.

Regarding this argument it is the position of the examiner that upon further consideration of specification, it does not appear that the cholesterol relied upon by applicant has a statistically significant effect on the uptake of pigments, and therefor the product of the instant claims does not have a patentable distinction between the invention of Iwahashi and that of the instant claims. The effect of cholesterol is not fully explained or established in the specification. The examples refer to Table 2, which recites experimental data for feed composition with and without cholesterol. However the standard deviations reported in the table indicate a statistical overlap. This overlap brings into question the statistical significance of the data reported. With no significant statistical difference in the plasma concentrations it is the position of the examiner that there exist no significance for the presence of cholesterol in the feed composition. In keeping with the teachings of '130, cholesterol had no significant effect. Also under question are the number of tested by applicant. According the specification, two samples from each group (with and without cholesterol) were run through statistical analysis. Two samples are far too few to arrive at a significant enough conclusions regarding an experimental question. It is unclear if more samples were run, and if so, what data was retrieved. In view of these aspects, it is the position of the examiner that the claims will remain obviated by the '130 reference. The reference though discloses a feed composition to a different fish species, does explicitly teach

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method of feeding fish cholesterol. Until such time where the data of the instant claims can be more clearly defined the instant claims shall remain obviated. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

#### Conclusion

Claims 1,3,4 and 12 have been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young Examiner Art Unit 1615

MP Young

Thurmany K. Page Supe<del>rvisory Patent Examiner</del> Technology Center 1600